Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 210

Report Date:10/04/2007

Study Summary

Laboratory	Study	Study Start	Length of Study	Number of Animals Total and	Number Surviving and (Mean	Maximum Mean Weekly Body	
Name	Number	Date	in Days	(#/Cage)	Life Span)	Weight	Chemical
				M	ale		
Southern Research Institute	052011407	10/02/02	730	50 (3)	28(696)	532.4	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601905	09/26/01	729	50 (3)	31(686)	526.0	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute Southern Research Institute	059601803 059601705	12/15/98 03/08/00	729 729	50 (3) 50 (3)	29(682) 34(683)	511.6 522.9	Water disinfection byproducts (Bromodichloromethane) Water disinfection byproducts (Dibromoacetic acid)
Southern Research Institute	059601705	09/05/01	729	50 (3)	31(692)	507.8	Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601003	09/16/98	729	50 (3)	36(687)	514.1	Water disinfection byproducts (Sodium chlorate)
				Fer	nale		
Southern Research Institute	052011407	10/02/02	735	50 (5)	33(700)	351.2	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601905	09/26/01	731	50 (5)	34(688)	357.3	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute Southern Research Institute	059601803 059601705	N/A 03/08/00	N/A 734	0 (0)	0(0)	N/A	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute	059601705	03/06/00	734 734	50 (5) 50 (5)	35(693) 29(689)	350.5 337.6	Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601003	09/05/01	734	50 (5)	37(699)	341.7	Water disinfection byproducts (Sodium chlorate)
		22.10/00		(0)	- (555)		

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 211

			Male				Female	
All Organs: Benign Tumors								
_ · · · · · · · · · · · · · · · · · · ·		49/50 (98%)	50/50 (100%)	49/50 (98%)		47/50 (94%)	49/50 (98%)	
		47/50 (94%)	50/50 (100%)	48/50 (96%)		42/50 (84%)	44/50 (88%)	46/50 (92%)
verall Incidence	Total	293/300 (97.67%)	Mean 97.67%	SD 2.34%	Total	228/250 (91.2%)	Mean 91.2%	SD 5.4%
All Organs: Malignant Tumors								
_		29/50 (58%)	27/50 (54%)	28/50 (56%)		20/50 (40%)	18/50 (36%)	
		29/50 (58%)	27/50 (54%)	27/50 (54%)		16/50 (32%)	20/50 (40%)	21/50 (42%)
verall Incidence	Total	167/300 (55.67%)	Mean 55.67%	SD 1.97%	Total	95/250 (38%)	Mean 38%	SD 4%
All Organs: Malignant and Benign T	umors			•••••		•••••		
		50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%)	49/50 (98%)	
		50/50 (100%)	50/50 (100%)	49/50 (98%)		45/50 (90%)	48/50 (96%)	49/50 (98%)
verall Incidence	Total	299/300 (99.67%)	Mean 99.67%	SD 0.82%	Total	240/250 (96%)	Mean 96%	SD 3.46%
All Organs: Hemangioma								
· ·		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma	•••••							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0.700 (00.1)
	+	0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

sion: Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 212

			Male				Female	
All Organs:	mangiams							
Hemangiosarcoma or He	nangioma	1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
All Organs: Histiocytic Sarcoma					• • • • • • • • • • • • • • • • • • • •			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
fAll Organs: Leukemia: Lymphocytic, Undifferentiated	•	26/50 (52%) 17/50 (34%)	21/50 (42%) 21/50 (42%)	16/50 (32%) 13/50 (26%)		8/50 (16%) 11/50 (22%)	15/50 (30%) 14/50 (28%)	11/50 (22%)
Overall Incidence	Total	114/300 (38%)	Mean 38%	SD 9.21%	Total	59/250 (23.6%)	Mean 23.6%	SD 5.55%
fAll Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T	stiocytic, Lyn			0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
All Organs: Mesothelioma: Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 213

			M	ale						Fema	le		
All Organs: Mesothelioma: Benign, Malic	nant NOS	<u> </u>											
Mesotrichoma. Berngn, Mang	jiiaiit, itoc	, 2/50 (4%	5) 1/50	(2%)	3/50	(6%)		0/50	(0%)	0/50	(0%)		
		3/50 (6%		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	9/300 (3%)		1 3%		2.76%	Total	0/250 (0	,	Mean		SD	
All Organs: Mesothelioma: Malignant						•••••	•••••						•••••
_		2/50 (4%	,	(2%)	3/50	(6%)		0/50	(0%)	0/50	(0%)		
		3/50 (6%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	9/300 (3%)	Mear	ո 3%	SD	2.76%	Total	0/250 (0	%)	Mean	0%	SD	0%
All Organs: Osteoma											•••••		
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
overall Incidence	Total	0/300 (0%)	Mear	ո 0%	SD	0%	Total	0/250 (0	%)	Mean	0%	SD	0%
All Organs: Osteosarcoma													
		0/50 (0%	5) 0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)		
		0/50 (0%	0/50	(0%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/300 (1%)		n 1%		2.45%	Total	`	.4%)		0.4%		0.89%
#All Organs: Osteosarcoma or Osteoma												•••••	
		0/50 (0%		(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(00()
S	T-1-1	0/50 (0%	,	(0%)	3/50	(6%)	T-1-1	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/300 (1%)	Mear	า 1%	SD	2.45%	Total	1/250 (0	.4%)	Mean	0.4%	SD	0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 214

			Male				Female	
*Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/49 (0%) 0/298 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	1/49 (2%) 2/249 (0.8%)	0/50 (0%) Mean 0.81%	0/50 (0%) SD 1.11%
*Adrenal Cortex:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/49 (0%) 0/298 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		,				,		
*Adrenal Medulla: Ganglioneuroma								
3		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	
	-	0/49 (0%)	0/50 (0%)	0/49 (0%)	-	0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma								
riemangioma		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benigr					•••••			
Delingi	•	6/49 (12%)	9/50 (18%)	8/50 (16%)		2/49 (4%)	2/49 (4%)	
		7/49 (14%)	10/50 (20%)	6/49 (12%)		1/49 (2%)	1/49 (2%)	2/50 (4%)
Overall Incidence	Total	46/297 (15.49%)	Mean 15.46%	SD 3.14%	Total	8/246 (3.25%)	Mean 3.25%	SD 1.1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 215

			Male				Female	
Adrenal Medulla:	2							
Pheochromocytoma (omplex	0/49 (0%)	0/50 (0%)	2/50 (4%)		0/49 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/297 (0.67%)	Mean 0.67%	SD 1.63%	Total	0/246 (0%)	Mean 0%	SD 0%
Adrenal Medulla:	•••••							
Pheochromocytoma M	V alignant							
		1/49 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%)	2/49 (4%)	0/50 (00/)
	-	0/49 (0%)	0/50 (0%)	3/49 (6%)	+	0/49 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	6/297 (2.02%)	Mean 2.03%	SD 2.24%	Total	3/246 (1.22%)	Mean 1.22%	SD 1.83%
Adrenal Medulla:		•••••					•••••	
Pheochromocytoma:	Benign, Complex							
		7/49 (14%)	10/50 (20%)	11/50 (22%)		3/49 (6%)	4/49 (8%)	0/50 /40/)
Overall Incidence	Total	7/49 (14%)	10/50 (20%)	9/49 (18%)	Total	1/49 (2%)	1/49 (2%)	2/50 (4%)
	Total	54/297 (18.18%)	Mean 18.16%	SD 3.21%	Total	11/246 (4.47%)	Mean 4.47%	SD 2.66%
Blood Vessel:								
Osteosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
······································		,				` ,		
Bone: Chondrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 216

			Male				Female	
#Bone: Chondrosarcoma or Chond	roma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	0/50 (0%) SD 0.89%
Bone: Chordoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Bone: Osteosarcoma					•••••			
Osteosarooma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 217

Overall Incidence Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/249 (0%) Mean 0% SD 0% *Brain: Ependymoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)<				Male				Female	
0/50 0/96 0/50 0/96 0/50 0/96									
Deveral Incidence	3								
Brain: Ependymoma Benign			` ,	` '	(,		` ,	` ,	` '
Brain: Ependymoma Benign			,				` ,		
O/50 (0%) O/50	Brain:								
Display								` ,	2/12 (22/)
Brain: Glioma Malignant 0/50 (0%) 0			` ,	` '	(,		` ,	` ,	` '
Glioma Malignant 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	verall incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)				•••••					
Display	_		` ,	` ,			()	` ,	
Brain:			` ,	` '	` '		` ,	` ,	` '
Granular Cell Tumor Benign 0/50 (0%)	Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/249 (0%)	Mean 0%	SD 0%
0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 0/50 0/50 0/50 0/50 0/50 0/5									
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0% Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% Brain: Medulloblastoma Mal 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Grandiai Cen Tullioi Benigi		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Brain: Medulloblastoma Mal 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			` ,	` ,	()		` ,	()	0/49 (0%)
Brain: Medulloblastoma Mal 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
	Brain:					•••••			
0/50 $0/60$ $0/60$ $0/60$ $0/60$ $0/60$ $0/60$ $0/60$ $0/60$ $0/60$ $0/60$ $0/60$					(/			()	0/40 (09/)
Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0%	Overall Incidence	Total	` ,	` ,	` '	Total	` ,	` ,	` ,

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 218

							Female	
Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)	0/50 (0%)	0/40 (00/)
overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	0/49 (0%) SD 0.89%
Brain: Meningioma: Benign, Malig	nant, NOS							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/40 (00/)
verall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	0/49 (0%) SD 0.89%
verall incluence	ı olai	0/300 (0%)	Mean 0%	30 0%	I Olai	1/249 (0.4%)	iviean 0.4%	3D 0.69%
Brain: Oligodendroglioma Benign								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/12 (22/)
verall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
······	10tai				ı olai	0/249 (0/0)		
Brain: Oligodendroglioma Maligna	ınt							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma, Glioma		ytoma			•••••			
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/40 (00/)
verall Incidence	Total	1/50 (2%) 3/300 (1%)	0/50 (0%) Mean 1%	0/50 (0%) SD 1.67%	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
*Clitoral/Preputial Gland: Adenoma				
		4/50 (8%) 3/50 (6%)	4/50 (8%) 2/50 (4%) 1/48 (2%) 1/48 (2%)	2/50 (4%) 17/50 (34%) 8/50 (16%) 5/50 (10%) 11/49 (22%)
Overall Incidence	Total	15/296 (5.07%)	Mean 5.03% SD 2.72%	Total 43/249 (17.27%) Mean 17.29% SD 11.59%
*Clitoral/Preputial Gland: Carcinoma				
		1/50 (2%) 0/50 (0%)	2/50 (4%) 1/50 (2%) 0/48 (0%) 3/48 (6%)	8/50 (16%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 3/49 (6%)
Overall Incidence	Total	7/296 (2.36%)	Mean 2.38% SD 2.42%	1/50 (2%) 1/50 (2%) 3/49 (6%) Total 13/249 (5.22%) Mean 5.22% SD 6.42%
Overall incluence	TOLAI	77290 (2.30%)	Wedii 2.30% SD 2.42%	10tal 13/249 (3.22%) Ivieal 3.22% SD 6.42%
*Clitoral/Preputial Gland: Carcinoma or Adenoma				
		4/50 (8%)	5/50 (10%) 3/50 (6%)	10/50 (20%) 17/50 (34%)
		3/50 (6%)	1/48 (2%) 4/48 (8%)	9/50 (18%) 6/50 (12%) 14/49 (29%)
Overall Incidence	Total	20/296 (6.76%)	Mean 6.74% SD 2.74%	Total 56/249 (22.49%) Mean 22.51% SD 8.74%
*Clitoral/Preputial Gland: Fibrosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Occupation and desired	T-1-1	0/50 (0%)	0/48 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0% SD 0%	Total 0/249 (0%) Mean 0% SD 0%
	• • • • • • • • • • • • • • • • • • • •	•••••		
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/48 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.33% SD 0.82%	Total 0/249 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 219

^{#:} Denominator is number of animals necropsied

SISIOII. OCIZUUI

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 220

		Male				Female	
	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
							0/50 (0%)
Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	` ,	` '	` '		(,	` '	0/50 (0%)
Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
enign							
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	` ,	` '	` ,		(,	` '	0/50 (0%)
	` ,				,		SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	` ,			Total	0/250 (0%)	Mean 0%	SD 0%
							0/50 (0%)
Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
-	Total Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Penign 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Total 0/300 (0%) Total 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total 1/300 (0.33%) Mean 0.33% O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/300 (0%) Mean 0% Penign O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/300 (0%) Mean 0% O/50 (0%) O/50 (0%) Total O/300 (0%) Mean 0% Total O/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/300 (0.33%) Mean 0.33% SD 0.82% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0% Panign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (0%) Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0% Total	0/50 (0%) 0/50	O/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Harderian Gland: Adenoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% 0/250 (0%) Mean 0% SD 0% Total #Harderian Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%) 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0.33% SD 0.82% 0/250 SD 0% 1/300 (0.33%) Total Mean 0% #Harderian Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 0/250 Mean 0% *Heart: Schwannoma Benign 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** 1/300 (0.33%) SD 0.82% SD 1.1% Total Mean 0.33% Total 2/250 (0.8%)Mean 0.8% *Heart: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%)Mean 0% SD 0% Total 1/250 (0.4%)Mean 0.4% SD 0.89%

Page: 221

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 222

			Male				Female	
fIntestine Large: Colon/Rectum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/=0 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/Rectum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Large: Colon/Rectum: Carcinoma or Adenoma			•••••					•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Large: Colon/Rectum: Leiomyosarcoma			•••••		•••••			
Leiomyodarooma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Duodenum: Carcinoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Normall Impidance	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 223

			Male				Female	
Intestine Small: Duodenum: Leiomyoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/=0 (00:)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/=0 (00/)
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Unspeci								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 224

			Male				Female			
#Intestine Small: Site Unspecified: Leiomyoma										
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
Intestine Small: Site Unspeci										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
Islets, Pancreatic: Adenoma				•••••			•••••			
		4/50 (8%)	3/50 (6%)	3/49 (6%)		2/50 (4%)	3/49 (6%)			
		5/48 (10%)	5/49 (10%)	3/50 (6%)		0/47 (0%)	1/50 (2%)	2/50 (4%)		
Overall Incidence	Total	23/296 (7.77%)	Mean 7.79%	SD 2.1%	Total	8/246 (3.25%)	Mean 3.22%	SD 2.32%		
Islets, Pancreatic:				•••••						
		0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	0/49 (0%)			
		0/48 (0%)	1/49 (2%)	2/50 (4%)		0/47 (0%)	0/50 (0%)	1/50 (2%)		
verall Incidence	Total	5/296 (1.69%)	Mean 1.67%	SD 1.97%	Total	1/246 (0.41%)	Mean 0.4%	SD 0.89%		
Islets, Pancreatic: Carcinoma or Adenoma	•••••									
		4/50 (8%)	5/50 (10%)	3/49 (6%)		2/50 (4%)	3/49 (6%)	0/50 (001)		
	-	5/48 (10%)	6/49 (12%)	5/50 (10%)	-	0/47 (0%)	1/50 (2%)	3/50 (6%)		
Overall Incidence	Total	28/296 (9.46%)	Mean 9.46%	SD 2.12%	Total	9/246 (3.66%)	Mean 3.62%	SD 2.64%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 225

Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
*Kidney: Pelvis and Transit Carcinoma	tional Epitheliui		0/50 (001)	(00)	0/50 (00/)	
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 0/49 (0%) 0/47	(0%) (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0% SD ()% Total	0/250 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transit Carcinoma or Adenoma	tional Epitheliui					
		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/49 (0%)	0/49 (0%) 0/47 Mean 0% SD 0	(0%)	0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%
	Total	0/294 (0%)	iviean 0% SD (SD 0%
*Kidney: Pelvis and Transi Papilloma						
·		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%)	0(50 (00))
Overall Incidence	Total	0/49 (0%) 0/294 (0%)	0/49 (0%) 0/47 Mean 0% SD 0	(0%)	0/50 (0%) 0/50 (0%) 0/250 (0%) Mean 0%	0/50 (0%) SD 0%
	Total	,	Wealt 0% SD (,	3D 0%
Kidney: Renal Tubule: Adenoma						
		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 1/50 (2%)	0/50 (00/)
Overall Incidence	Total	1/49 (2%) 1/294 (0.34%)	0/49 (0%) 0/47 Mean 0.34% SD 0	(0%)).83% Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%) Mean 0.4%	0/50 (0%) SD 0.89%
Werall incluence	TOTAL	1/294 (0.34%)	iviean 0.34% SD (7.03% Total	1/250 (0.4%) Weatt 0.4%	3D 0.09%
Kidney: Renal Tubule: Carcinoma						•••••
		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%)	
Overell Incidence	Total	0/49 (0%)	0/49 (0%) 0/47	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0% SD 0	0% Total	0/250 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 226

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	
		1/49 (2%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/294 (0.34%)	Mean 0.34%	SD 0.83%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma				•••••		•••••	•••••	
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Liposarcoma				•••••		•••••		
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Beni		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

SISIOII. OCIZOO7

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 227

			Male				Female	
Kidney: Renal Tubule: Nephroblastoma								
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0./50 (004)
	T-1-1	0/49 (0%)	0/49 (0%)	0/47 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
_iver: Cholangiocarcinoma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
iver: Cholangioma			•••••	•••••		•••••		
Onolangionia		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 228

			Male				Female	
Liver: Hepatocellular Adenoma		2/22 (22)		(224)			2/22 (22)	
		0/50 (0%) 1/50 (2%)	2/50 (4%) 1/5 0/50 (0%) 0/5	` '		1/50 (2%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	` '	SD 1.63%	Total	3/250 (1.2%)	Mean 1.2%	0/50 (0%) SD 1.79%
Liver: Hepatocellular Carcinoma								
•		0/50 (0%)	0/50 (0%) 0/5			0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/5	` ,		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinoma	or Hepatob	lastoma						
		0/50 (0%)	0/50 (0%) 0/5			0/50 (0%)	0/50 (0%)	0/50 (00/)
O	T-1-1	0/50 (0%)	0/50 (0%) 0/5	` ,	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinoma	or Hepatoc	ellular Adenoma						
		0/50 (0%)	2/50 (4%) 1/5	0 (2%)		1/50 (2%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%) 0/5	` ,		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
Liver: Hepatocellular Carcinoma Hepatoblastoma	, Hepatocell	ular Adenoma, or						
		0/50 (0%)	2/50 (4%) 1/5			1/50 (2%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%) 0/5	` ,		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 229

			Male				Female	
*Lung: Alveolar/Bronchiolar Ad	lonoma							
Aiveolai/Biolicillolai Ac	leliollia	4/50 (8%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	1/50 (2%)	
		2/50 (4%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/300 (4%)	Mean 4%	SD 2.83%	Total	8/250 (3.2%)	Mean 3.2%	SD 2.68%
Lung: Alveolar/Bronchiolar Ca	ırcinoma						•••••	•••••
7		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 2.19%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Alveolar/Bronchiolar Ca Adenoma Overall Incidence	rcinoma or Alv Total	4/50 (8%) 2/50 (4%) 18/300 (6%)	3/50 (6%) 4/50 (8%) Mean 6%	1/50 (2%) 4/50 (8%) SD 2.53%	Total	4/50 (8%) 2/50 (4%) 10/250 (4%)	1/50 (2%) 1/50 (2%) Mean 4%	2/50 (4%) SD 2.45%
Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overell Incidence	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 230

			Male				Female	
Lung: Squamous Cell Carcinoma								
·		0/50 (0%)		/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	` '	/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%)		/50 (0%)		0/50 (0%)	0/50 (0%)	2 (22 (22)
		0/50 (0%)	` '	/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%)		/50 (2%)		2/50 (4%)	0/50 (0%)	
		0/50 (0%)	` '	/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	5/250 (2%)	Mean 2%	SD 2.83%
Mammary Gland: Carcinoma								
		1/50 (2%)	0/50 (0%) 0	/50 (0%)		0/50 (0%)	1/50 (2%)	
		1/50 (2%)	1/50 (2%) 0	/50 (0%)		3/50 (6%)	2/50 (4%)	3/50 (6%)
overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	9/250 (3.6%)	Mean 3.6%	SD 2.61%
Mammary Gland: Carcinoma or Adenoma								
		1/50 (2%)		/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 /4000
N	T-1-1	1/50 (2%)	` '	/50 (0%)	T-1-1	3/50 (6%)	2/50 (4%)	6/50 (12%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	14/250 (5.6%)	Mean 5.6%	SD 3.85%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 231

			Male				Female	
Mammary Gland:								
Fibroadenoma		2/50 (4%)	3/50 (6%)	1/50 (2%)		37/50 (74%)	43/50 (86%)	
		4/50 (8%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	33/50 (66%)
verall Incidence	Total	18/300 (6%)	Mean 6%	SD 3.58%	Total	176/250 (70.4%)	Mean 70.4%	SD 9.84%
Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenor	ma or Adenoma							
		2/50 (4%)	3/50 (6%)	2/50 (4%)		37/50 (74%)	43/50 (86%)	0=(=0 (=00)
		4/50 (8%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	35/50 (70%)
verall Incidence	Total	19/300 (6.33%)	Mean 6.33%	SD 3.2%	Total	178/250 (71.2%)	Mean 71.2%	SD 9.55%
Mammary Gland: Fibroma, Fibroadenor	na. Carcinoma. o	or Adenoma						
	.,	3/50 (6%)	3/50 (6%)	2/50 (4%)		37/50 (74%)	43/50 (86%)	
		5/50 (10%)	6/50 (12%)	2/50 (4%)		32/50 (64%)	31/50 (62%)	37/50 (74%)
verall Incidence	Total	21/300 (7%)	Mean 7%	SD 3.29%	Total	180/250 (72%)	Mean 72%	SD 9.59%
Mesentery: Fibrosarcoma							•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 232

			Male				Female	
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mesentery: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (004)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Mesentery: Rhabdomyosarcoma					•••••			
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Adenoma					•••••			
Auerionia		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Chondroma	•••••				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/49 (0%)	0/50 (0%)	0/49 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
verali incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Nose:								
Sarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcin	oma				•••••			
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Papilloma Squamous o		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%
Oral Cavity (Oral Mucosa Squamous Cell Carcin	, Tongue, Phary				• • • • • • • • • • • • • • • • • • • •			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/=0 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma		nx, Tooth, Gingiva):			•			
- I		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

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Report Date: 10/04/2007

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female #Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%) 0/50 0/50 0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Oral Mucosa: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total SD 0.89% 0/300 (0%) 1/250 (0.4%) Mean 0.4% *Ovary: **Granulosa Cell Tumor Benign** 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** SD 0.89% Total 1/249 (0.4%) Mean 0.4% *Ovary: **Granulosa Cell Tumor Malignant** 0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/249 Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 0/50 (0%)0/50 (0%)1/50 (2%)

.....

Total

1/249

(0.4%)

Mean 0.4%

SD 0.89%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male		Female
*Ovary: Granulosa-Theca Tumor B	enian				
Granaloca Trioca Tamor B	og			`	%) 0/50 (0%)
Overall Incidence				Total 1/249 (0.4%	<i>'</i>
*Pancreas:					
		1/50 (2%) 0/48 (0%)	2/50 (4%) 3/49 (6%) 1/49 (2%) 0/49 (0%)	`	%) 0/50 (0%) %) 0/50 (0%) 2/50 (4%)
Overall Incidence	Total	7/295 (2.37%)	Mean 2.36% SD 2.38%	Total 2/247 (0.81	, , , , , , , , , , , , , , , , , , , ,
*Pancreas: Carcinoma					
		0/50 (0%)	0/50 (0%) 0/49 (0%)	`	%) 0/50 (0%)
Overall Incidence	Total	0/48 (0%) 0/295 (0%)	0/49 (0%) 0/49 (0%) Mean 0% SD 0%	0/47 (0 Total 0/247 (0%)	%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Pancreas:					
Carcinoma or Adenoma		1/50 (2%)	2/50 (4%) 3/49 (6%)	0/50 (0	%) 0/50 (0%)
		0/48 (0%)	1/49 (2%) 0/49 (0%)	`	%) 0/50 (0%) 2/50 (4%)
Overall Incidence	Total	7/295 (2.37%)	Mean 2.36% SD 2.38%	Total 2/247 (0.81	,
*Pancreas: Mixed Tumor Benign					
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%)	•	%)
Overall Incidence	Total	0/295 (0%)	Mean 0% SD 0%	Total 0/247 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 236

			Male				Female	
Parathyroid Gland:								
Adenoma		0/46 (0%)	0/44 (0%)	0/48 (0%)		0/46 (0%)	0/42 (0%)	
		0/50 (0%)	1/46 (2%)	0/49 (0%)		0/50 (0%)	0/42 (0%)	0/47 (0%)
Overall Incidence	Total	1/283 (0.35%)	Mean 0.36%	SD 0.89%	Total	0/227 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant							•••••	
oomamoma mangnam		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, M Overall Incidence	alignant, NOS	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pituitary Gland: Pars Distali Adenoma				00/40 (45%)		00/50 /500/	00/50 (50%)	
		16/50 (32%) 23/50 (46%)	23/48 (48%) 24/50 (48%)	22/49 (45%) 16/48 (33%)		28/50 (56%) 26/50 (52%)	28/50 (56%) 27/49 (55%)	23/49 (47%)
Overall Incidence	Total	124/295 (42.03%)	Mean 42.02%	SD 7.36%	Total	132/248 (53.23%)	Mean 53.21%	SD 3.87%
Pituitary Gland: Pars Distali Carcinoma		ied Site: 0/50 (0%)	0/48 (0%)	0/49 (0%)		,		1/49 (2%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 16/50 (32%)(48%)22/49 (45%)(60%)(56%)23/50 (46%)24/50 (48%)16/48 (33%)26/50 (52%)27/49 (55%)24/49 (49%) **Overall Incidence** Total 124/295 (42.03%) Mean 42.02% SD 7.36% 135/248 (54.44%) Mean 54.42% SD 4.17% Total *Pituitary Gland: Pars Intermedia: Adenoma 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/48 (0%)1/50 (2%)0/49 (0%)1/49 (2%)**Overall Incidence** 0/295 (0%) Mean 0% SD 0% SD 1.11% Total Total 2/248 (0.81%) Mean 0.81% *Pituitary Gland: Pars Intermedia: Carcinoma 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%) 0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** SD 0% SD 0% Total 0/295 (0%) Mean 0% Total 0/248 (0%) Mean 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma (0%)0/50 (0%)0/48 (0%)0/49 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)1/50 (2%)0/49 (0%)(2%)**Overall Incidence** 0/295 (0%) SD 0% SD 1.11% Total Mean 0% Total 2/248 (0.81%) Mean 0.81% *Prostate: Adenoma (4%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%)Mean 0.67% SD 1.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
Prostate: Carcinoma or Adenoma				
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67% SD 1.63%	
Salivary Glands: Sarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Novell Incidence	Total	0/50 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
verall Incidence	Total	0/299 (0%)		Total 0/250 (0%) Mean 0% SD 0%
Salivary Glands: Schwannoma Malignant				
_		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
		` ,		10tal 0/250 (0/0) Mcall 0/0 0D 0/0
Skeletal Muscle: Fibrosarcoma				
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0.33% SD 0.82%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%
		1/300 (0.33%)		
Skeletal Muscle: Hemangioma				
·g		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Nuavall Incidence	Total	1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Tatal 0/250 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 239

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	- / / /
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (004)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma						•••••		
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or			•••••			•••••		
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
N	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 240 Report Date: 10/04/2007

			Male				Female	
Skin: Basal Cell Adenoma								
Busur Gen Auenoma		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin:	•••••							
Basal Cell Adenoma or E	Basosquamou		0/50 (00/)	4/50 (00/)		0/50 (00/)	0/50 (00/)	
		2/50 (4%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	0/250 (0%)	Mean 0%	SD 0%
		0,000 (1.07,70)	Wicaii 1.07 /0	05 1.07 70	rotai	0/200 (0/0)	Wicaii 070	05 070
Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous [·]	Tumor Benign, or 2/50 (4%) 1/50 (2%)	3/50 (6%) 2/50 (4%)	1/50 (2%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)
Overall Incidence	Total	10/300 (3.33%)	Mean 3.33%	SD 1.63%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
Skin:								
Basal Cell Carcinoma		0/50 (00/)	0/50 (00/)	4/50 (00/)		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
verall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
· · · · · · · · · · · · · · · · · · ·		47000 (1.0070)	Wican 1.0070	05 1.0070	- Total	17200 (0.470)	Wicair 0.470	0.0070
Skin: Basal Cell Carcinoma or NOS)	Basosquamo	us Tumor (malignant o	г					
-,		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 241

			Male				Female	
Skin: Basal Cell Carcinoma, Tumor (benign, malign								
(a	,,	2/50 (4%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
verall Incidence	Total	14/300 (4.67%)	Mean 4.67%	SD 2.07%	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%
Skin: Basal or Sq. Cell Carci or B), Basal Cell Adenc	oma, Adenoma,	Papilloma, Sq			•••••			
Papilloma, Keratoacan	tnoma, iricnoe	5/50 (10%)	6/50 (12%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	
		7/50 (14%)	11/50 (22%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	3/50 (6%)
verall Incidence	Total	38/300 (12.67%)	Mean 12.67%	SD 5.01%	Total	5/250 (2%)	Mean 2%	SD 2.45%
Skin: Fibroma Overall Incidence	Total	8/50 (16%) 5/50 (10%) 43/300 (14.33%)	7/50 (14%) 8/50 (16%) Mean 14.33%	6/50 (12%) 9/50 (18%) SD 2.94%	Total	1/50 (2%) 1/50 (2%) 7/250 (2.8%)	1/50 (2%) 0/50 (0%) Mean 2.8%	4/50 (8%) SD 3.03%
Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	a, Sarcoma, Myz	koma, Myxosarcoma, or						
· · · · · · · · · · · · · · · · · · ·		11/50 (22%)	8/50 (16%)	7/50 (14%)		1/50 (2%)	1/50 (2%)	
	_	6/50 (12%)	9/50 (18%)	10/50 (20%)	_	1/50 (2%)	1/50 (2%)	4/50 (8%)
verall Incidence	Total	51/300 (17%)	Mean 17%	SD 3.74%	Total	8/250 (3.2%)	Mean 3.2%	SD 2.68%
Skin: Fibrosarcoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00%)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Page: 242

			Male		Female						
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma											
•		3/50 (6%)	1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	1/50 (2%) 8/300 (2.67%)	1/50 (2%) 1/50 (2%) Mean 2.67% SD 1.63%	0/50 (0%) Total 1/250 (0.4%)	1/50 (2%) 0/50 (0%) Mean 0.4% SD 0.89%						
Skin:											
Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)						
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	,	Mean 0% SD 0%						
Skin: Hemangioma											
•		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)						
	-	1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)						
verall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.03%	, ,	Mean 0% SD 0%						
Skin: Hemangiosarcoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)						
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%						
		0,300 (070)		10101 0,200 (0,70)							
Skin: Keratoacanthoma											
		2/50 (4%)	1/50 (2%) 3/50 (6%)	1/50 (2%)	0/50 (0%)						
Overall Incidence	Total	3/50 (6%) 19/300 (6.33%)	6/50 (12%) 4/50 (8%) Mean 6.33% SD 3.44%	,	0/50 (0%) 0/50 (0%) Mean 0.4% SD 0.89%						
Jveran meracilee	i Otai	13/300 (0.33/8)	WCaii 0.3570 3D 3.4470	10(a) 1/200 (0.470)	WCaii 0.470 3D 0.0370						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 243

			Male		Female	
Skin:						
Lipoma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	1/50 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
overall Incidence	Total	1/300 (0.33%)	` '	0 0.82% Total	1/250 (0.4%) Mean 0.4%	SD 0.89%
Skin: Liposarcoma						
•		0/50 (0%)	1/50 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD	0 0.82% Total	0/250 (0%) Mean 0%	SD 0%
Skin: Neural Crest Tumor						
		0/50 (0%)	1/50 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		1/50 (2%)	0/50 (0%) 1/50	(2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD	0 1.1% Total	1/250 (0.4%) Mean 0.4%	SD 0.89%
Skin: Neurofibroma or Schw	annoma benign					
	.	0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)		0 0% Total	0/250 (0%) Mean 0%	SD 0%
Skin: Neurofibrosarcoma or		malignant or NOS)				
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
Overell Incidence	Total	0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD	0 0% Total	0/250 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Report Date: 10/04/2007

Page: 244

			Male				Female				
Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)											
. J		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			
#Skin: Osteosarcoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin:	•••••										
Sarcoma		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 1.63%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin:	•••••		•••••								
Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			
#Skin: Schwannoma Malignant											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 245

			Male				Female	
#Skin:								
Squamous Cell Carcinom	a	4/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/250 (0%)	Mean 0%	SD 0%
		_,, (e.e. , , ,				0,200 (0,0)		02 070
¢Skin:								
Squamous Cell Carcinom								
Basosquamous Tumor (m	alignant or r	1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	2/50 (4%)	0/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
,		3,000 (1.07,0)	WOOT 1.07 /0	1.0170	10141	1,200 (0.470)	WIGGIT 0.470	0.0070
¢Skin:								
Squamous Cell Papilloma								
		1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin:								
Squamous Cell Papilloma	or Papillom	a						
•	•	1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin:			•••••					•••••
Squamous Cell Papilloma		Squamous Cell						
Carcinoma or Keratoacan	tnoma	4/50 (99/)	4/50 (89/.)	3/50 (69/.)		1/50 (20/)	0/50 (0%)	
		4/50 (8%) 6/50 (12%)	4/50 (8%) 7/50 (14%)	3/50 (6%) 4/50 (8%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
		0/30 (12%)	1/50 (14/0)	-1 /30 (0/0)		1/30 (2/0)	0/30 (0/0)	0/30 (0/0)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 246

			Male				Female			
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma										
	, - ара,	3/50 (6%)	4/50 (8%)	3/50 (6%)		1/50 (2%)	0/50 (0%)			
		5/50 (10%)	7/50 (14%)	4/50 (8%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	26/300 (8.67%)	Mean 8.67%	SD 3.01%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%		
Skin:										
Trichoepithelioma										
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (40/)		
	-	1/50 (2%)	0/50 (0%)	1/50 (2%)	-	0/50 (0%)	0/50 (0%)	2/50 (4%)		
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%		
Skin: Sebaceous Gland: Adenoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		
#Skin: Sebaceous Gland: Carcinoma										
Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 247

			Male				Female	
Spinal Cord: Astrocytoma Benign		0/50 (00/)	0/50 (00/)	0/50 /00/)		0/50 (00/)	0/50 /00/	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
verall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` ,				` ,		
Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Normall Institutes	Tatal	0/50 (0%)	0/49 (0%)	0/48 (0%)	Tatal	0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma			•••••			•••••		
•		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma			•••••			•••••		
G		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/295 (0.34%)	Mean 0.35%	SD 0.85%	Total	0/247 (0%)	Mean 0%	SD 0%
Spleen: Leiomyosarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Verall Incidence	Total	0/50 (0%)	0/49 (0%)	0/48 (0%)	Total	0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 248

			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0 (=0 (00))
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0 (=0 (00))
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Forestomach:	B W							•••••
Squamous Cell Carcinoma	or Papillon	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female
#Stomach, Glandular: Leiomyosarcoma							
·		0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0% SD 0%
#Stomach, Glandular: Lipoma	•••••						
		1/50 (2%) 0/50 (0%)	` ,	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0% SD 0%
*Testes:	•••••						
		48/50 (96%)		45/50 (90%)			
Overall Incidence	Total	41/50 (82%) 274/300 (91.33%)	49/50 (98%) 4 Mean 91.33%	45/50 (90%) SD 5.61%			
*Thymus: Sarcoma	•••••						
		0/48 (0%)	()	0/48 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/49 (2%) 1/285 (0.35%)	0/43 (0%) (Mean 0.34%	0/48 (0%) SD 0.83%	Total	0/49 (0%) 0/246 (0%)	0/48 (0%) 0/49 (0%) Mean 0% SD 0%
*Thymus: Thymoma Benign		0/40 (00/)	0/40 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)
		0/48 (0%) 1/49 (2%)	()	0/48 (0%) 0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%) 0/49 (0%)
Overall Incidence	Total	1/285 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/246 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 249

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 250

			Male				Female	
Thymus: Thymoma Malignant								
		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/43 (0%)	0/48 (0%) 0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/40 (09/)
Overall Incidence	Total	0/49 (0%)	Mean 0%	0/48 (0%) SD 0%	Total	0/49 (0%) 0/246 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/40 (00/)
Overall Incidence	Total	1/49 (2%) 1/285 (0.35%)	0/43 (0%) Mean 0.34%	0/48 (0%) SD 0.83%	Total	0/49 (0%) 0/246 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
		1/200 (0.00/0)	Wicaii 0.0470	0.0070		0/240 (0/0)		
Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%)	3/50 (6%)	8/46 (17%)		8/50 (16%)	6/49 (12%)	
Overall Incidence	Total	6/50 (12%)	10/49 (20%)	9/47 (19%)	Total	6/50 (12%)	6/46 (13%)	12/47 (26%) SD 5.69%
Overall Incidence	Total	41/292 (14.04%)	Mean 14.16%	SD 5.71%	Total	38/242 (15.7%)	Mean 15.76%	SD 5.69%
Thyroid Gland: C-Cell: Carcinoma							•••••	•••••
Gu . GG		1/50 (2%)	1/50 (2%)	1/46 (2%)		2/50 (4%)	1/49 (2%)	
S	T-1-1	1/50 (2%)	1/49 (2%)	2/47 (4%)	T-1-1	0/50 (0%)	0/46 (0%)	1/47 (2%)
Overall Incidence	Total	7/292 (2.4%)	Mean 2.41%	SD 0.91%	Total	4/242 (1.65%)	Mean 1.63%	SD 1.68%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Sarsinoma of Auctionia		6/50 (12%)	4/50 (8%)	9/46 (20%)		10/50 (20%)	7/49 (14%)	
		7/50 (14%)	11/49 (22%)	11/47 (23%)		6/50 (12%)	6/46 (13%)	13/47 (28%)
Overall Incidence	Total	48/292 (16.44%)	Mean 16.57%	SD 6.18%	Total	42/242 (17.36%)	Mean 17.4%	SD 6.52%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 251

			Male	Female
Thyroid Gland: Follicular Cell: Adenoma				
		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/46 (0%) 0/49 (0%) 1/47 (2%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 1/46 (2%) 0/47 (0%)
Overall Incidence	Total	4/292 (1.37%)	Mean 1.35% SD 1.64%	Total 1/242 (0.41%) Mean 0.43% SD 0.97%
Thyroid Gland: Follicular Cell: Carcinoma				
		0/50 (0%)	1/50 (2%) 0/46 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/50 (0%) 1/292 (0.34%)	0/49 (0%) 0/47 (0%) Mean 0.33% SD 0.82%	0/50 (0%) 0/46 (0%) 1/47 (2%) Total 1/242 (0.41%) Mean 0.43% SD 0.95%
Werall incluence	Total	1/292 (0.3476)	Wear 0.33% 3D 0.02%	10tal 1/242 (0.41%) Wealt 0.43% 3D 0.93%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma				
		0/50 (0%)	3/50 (6%) 0/46 (0%)	0/50 (0%) 0/49 (0%)
	Taral	1/50 (2%)	0/49 (0%) 1/47 (2%)	0/50 (0%) 1/46 (2%) 1/47 (2%)
verall Incidence	Total	5/292 (1.71%)	Mean 1.69% SD 2.34%	Total 2/242 (0.83%) Mean 0.86% SD 1.18%
Tissue NOS: Fibrosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
	Taral	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0% SD 0%
Tissue NOS: Leiomyoma				
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Nevall Incidence	Total	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/250 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 252

			Male				Female	
Tissue NOS: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
N	T - (- 1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
	.	0/50 (0%)	0/50 (0%)	1/50 (2%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/250 (0%)	Mean 0%	SD 0%
Tissue NOS: Sarcoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant						•••••		
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Verall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 253

			Male				Female	
Tongue:								
Squamous Cell Carcinoma	or Papillon		0/50 (00/)	4/50 (00/)		4/50 (00/)	0/50 (00/)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (00/)
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
FTooth: Odontoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/249 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/249 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date:10/04/2007

Page: 254

Species: RATS Strain: F344

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Jrinary Bladder: Leiomyosarcoma		2/20 (20)	2/20 (20)			2/12 /22/2	(00)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)
verall Incidence	Total	0/297 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
rinary Bladder: Papilloma		0.770 (00.4)	2/22 (221)	2/12 /22/		2/12 (22/)	2(72 (224)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
		,		02 0,0		` ,		
Jterus: Adenoma								
						1/50 (2%)	0/50 (0%)	
					.	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Iterus:								
Carcinoma						0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
Jterus: Deciduoma Benign								
						0/50 (0%)	0/50 (0%)	0/50 (00/)
verall Incidence					Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
veran incluence					IUlal	0/230 (0%)	Mean 070	3D 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 255

Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangioma 0/50 (0%)0/50 (0%)(0%) (0%) (0%) 0/50 0/50 0/50 **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 Mean 0% **#Uterus: Polyp Stromal** (20%)(18%)4/50 (8%)13/50 (26%)9/50 (18%)**Overall Incidence** 45/250 (18%)SD 6.48% Total Mean 18% **#Uterus:** Sarcoma Stromal 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/250 (0.4%)Mean 0.4% SD 0.89%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 256

Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal (20%)9/50 (18%)4/50 (8%)13/50 (26%)10/50 (20%)**Overall Incidence** Total 46/250 (18.4%) Mean 18.4% SD 6.54% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) SD 0.89% Mean 0.4% #Vagina: Polyp 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 Mean 0% #Vagina: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/250 #Zymbal's Gland: Adenoma (0%)(0%)(0%)0/50 0/50 (0%)(0%)1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%)Mean 0.33% SD 0.82% Total 0/250 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 257

			Male			
#Zymbal's Gland: Carcinoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	` ,	` ,
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total 2/250 (0.8%)	Mean 0.8% SD 1.1%
#Zymbal's Gland: Carcinoma or Adenoma						
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total 2/250 (0.8%)	Mean 0.8% SD 1.1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied